DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-612/S-026
NDA 20-066/S-008

GlaxoSmithKline Consumer Healthcare
Attention: David Schifkovitz
Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Mr. Schifkovitz:

Please refer to your supplemental new drug applications dated February 22, 1999, received February 23, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicorette 2mg and 4mg Gum, Original and Mint Flavored.

We acknowledge receipt of your submissions dated April 18, 2000 and April 16, 2001.

These supplemental new drug applications provide for labeling format changes into the Drug Facts format for both the original and mint flavored gum and changes in the carton that are consistent with the Nicorette 2mg and 4mg orange flavored gum that was approved September 25, 2000.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, these supplemental applications are approved effective on the date of this letter.

- The phrase "Nicorette User's Guide" must be added to the cover of the user's guide. This change can be made within 180 days or at the time of the next printing.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (carton labels, refill carton labels, Committed Quitters brochure, audio transcript and Users Guide submitted April 16, 2001) and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of these applications

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 18-612/S-026, 20-066/S-008." Approval of these submissions by FDA is not required before the labeling is used.

NDA 20-066/S-008

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Daniel P. Keravich, M.S., M.B.A., Regulatory Health Project Manager, at 301-827-2248.

Sincerely,

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research